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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,685	11/07/2001	Kurt E. Petersen	22660-0019 DIV 2	1753

7590 08/01/2003

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 08/01/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/005,685

Applicant(s)

PETERSEN ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 54-63, 65-68, 70-75, 77-90, 92-108, 110-136 and 215-230 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 117-136, 227 and 228 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 57, 61, 73, 83, 85, 101, 103, 229 and 230 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims rejected are 54-56,58,59,62,63,65-68,70-72,74,75,77-82,84,86-90,92-100,102,104-108,110-116 and 215-226.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 May 2003 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 57, "the chemical reaction" lacks antecedent basis. Note claim 55 has been amended to remove the word "chemically".

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 54-56, 58-60, 62, 63, 65-68, 70, 74, 75, 77-82, 84, 86-90, 92-96, 99, 100, 102, 104-108 and 110-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026).

The reference of Anderson et al. discloses a nucleic acid purification method which includes a cell lysing region, a nucleic acid capture region, a reaction chamber (connected or coupled to the other chambers), a detection chamber and a reagent chamber connected to the reaction chamber (See column 6, line 44 to column 12, line 45). With respect to the solid phase binding within the lysing region, the reference discloses the use of posts (1908) and binding

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reagents (1912). With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (See column 7, line 20 and Fig. 28). The reference discloses the use of a reagent chamber prior to amplifying the purified nucleic acids (See column 10, lines 34-39).

With respect to claims 54, while the reference of Anderson et al. discloses a step of forcing a sample to flow through the lysing chamber, the reference is silent as to the relative volume of the sample with respect to the volume of the lysis chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12).

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells.

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysis chamber.

With respect to the claimed filter of claim 54, the binding properties of the chamber of the reference of Anderson et al. inherently imply that the chamber functions as filter.

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Additionally, the reference of Wilding et al. discloses the use of a filter structure (18) that can include specific binding as employed by the primary reference is known in the art. As a result, it would have been obvious to one of ordinary skill in the art to employ a filter in the chamber of the primary reference for the known and expected result of providing a means recognized in the art for enriching a channel.

With respect to claims 55, 56, 58, 60, 62, 63, 82, 84, 86, 100, 102 and 104, the reference of Anderson et al. discloses steps of amplification, adding reagents, detection of analyte and the use of ultrasonic energy (See the discussion above with respect to the disclosure of Anderson et al.).

With respect to the use of agitating particles or beads of claims 65, 87 and 105, the reference of Anderson et al. discloses the use of lysing particles in the chamber (See column 7, lines 1-7).

With respect to the presence of a lysing buffer of claims 66, 88 and 106, it would have been obvious to one of ordinary skill in the art to provide reagents and/or buffers which are proper for creating the proper environment for cell lysing while maintaining the viability of the sample and efficiency of the system.

With respect to the use of an ultrasonic horn of claims 67, 89 and 107, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum transducer to employ so as to create the proper ultrasonic energy required for efficient cell lysis.

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With respect to the washing of claim 68 and capture material of claims 70, 96 and 114, the reference of Anderson et al. discloses solid phase binding of nucleic acids and washing (See column 7, lines 23-52).

With respect to claim 74, 81 and 99, the reference of Nelson et al. discloses a nucleic acid capture configuration and method of use that includes a waste chamber and discloses enriching the sample containing the nucleic acid target by using the disclosed enrichment configuration.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to enrich the nucleic acids released from the lysing chamber of the modified primary reference of Anderson et al. for the known and expected result of providing the advantages associated with the configuration of the enrichment process of Nelson et al. over a “on-line” or “single flow path” (column 1, lines 55-66) employed by Anderson et al. That is, all of the sample fluid flows through the detection portion of the device.

With respect to the volumes of sample relative to the volume of the capture chamber recited in claims 75, 79, 80, 90, 94, 95, 108, 112 and 113, the reference of Nelson et al. discloses that the enrichment channel serves to place the analyte of interest into a smaller volume than the initial sample volume, i.e. analyte concentrator (See column 4, lines 2-4). As a result, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed. Note the reference of Nelson et al. discloses a chamber volume of 1pl to 1ul (See column 4, line 16) and sample volume of 100ul (See Example 1).

With respect to the volumes recited in claims 77, 78, 92, 93, 110 and 111, while still maintaining the benefits associated with enrichment disclosed by the reference of Nelson et al., it



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would have been obvious to one of ordinary skill in the art to determine the optimum volume of the lysis chamber and/or volume of sample to employ based merely on the concentration of the target analyte in the sample to be detected while maintaining the detection efficiency of the system.

With respect to claim 81, the configuration and method of use suggested by the references of Wilding et al. and Nelson et al. above would result in the use of a waste chamber and flow of sample through the lysing chamber into the waste chamber so as to achieve the enrichment properties discussed by the reference of Nelson et al. See the discussion above with respect to claim 54.

Claim 99 is similar to claim 81, however, claim 99 recites that the reaction vessel is coupled to the cartridge rather than part of the cartridge.

The reference of Wilding et al. discloses that a sample processing device (10) can be used in combination with a cartridge device (50) wherein the processing device is inserted into the cartridge device (See Figs. 4, 6A, 6B and 7).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to manufacture the system of the modified primary reference as a modular system as suggested by Wilding et al. for the known and expected result of allowing the system to be easily reconfigured based merely on the intended reaction to be performed.

8. Claims 71, 97, 115 and 215-226 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029) and

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Wilding et al.(US 5,726,026) taken further in view of Hansmann et al.(US 5,707,799) and Cantor et al.(US 5,795,714).

The combination of the references of Anderson et al., Nelson et al. and Wilding et al. has been discussed above.

With respect to claims 71, 97, 115 and 215, while the reference of Nelson et al. discloses a multitude of binding structures (See column 4, lines 24 to column 5, line 38) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to employ an array of structures extending into a chamber and having an aspect ratio (length to width) of at least 2:1 (See column 3, lines 47-55; column 6, lines 57-67; and column 9, lines 34-36) for capturing a desired analyte.

The reference of Cantor et al. discloses that it is known in the art that an array of binding probes can be used to capture nucleic acids for detection as is done in the reference of Hansmann et al. or the array of probes can be used to capture and elute a target analyte as is done in the reference of Swedberg et al. (See column 4, lines 17-25, and column 4, line 66, to column 5, line 10).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the array of structures disclosed by the reference of Hansmann et al. in the chamber of the primary reference of Nelson et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result,

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capture of a desired analyte. The reference of Hansmann et al. discloses the use of the array of structure is advantageous over other known art recognized capture devices because of its dimensional reproducibility (See column 1, lines 21-40).

With respect to claims 216-222, the reference of Anderson et al. discloses steps of amplification, adding reagents, detection of analyte and the use of ultrasonic energy (See the discussion above with respect to the disclosure of Anderson et al.).

With respect to the volumes of sample relative to the volume of the capture chamber recited in claims 223-226, the reference of Nelson et al. discloses that the enrichment channel serves to place the analyte of interest into a smaller volume than the initial sample volume, i.e. analyte concentrator (See column 4, lines 2-4). As a result, the specific volume of the sample employed would have been merely an obvious matter in design choice based on considerations such as the specifics of the analysis to be performed and/or the source of the sample to be analyzed. Note the reference of Nelson et al. discloses a chamber volume of 1pl to 1ul (See column 4, line 16) and sample volume of 100ul (See Example 1).

9. Claims 72, 98 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026) taken further in view of Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the references of Anderson et al., Nelson et al. and Wilding et al. has been discussed above.

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The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure and heat the chamber for the known and expected result of enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

10. Claims 72, 98 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026) taken further in view of Brunner et al.(US 5,777,141).

The combination of the references of Anderson et al., Nelson et al. and Wilding et al. has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 54-56, 58-60, 62, 63, 65-68, 70-72, 74, 75, 77-82, 84, 86-90, 92-100, 102, 104-108, 110-116 and 215-226 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-22 and 103-107 of copending Application No. 09/513,443 in view of Anderson et al.(US 6,168,948) or Wilding et al.(US 5,726,026 or 5,928,880).

Claims 18-22 and 103-107 of the claims of Application '443 encompass a method of separating an analyte from a fluid sample that includes an extraction region and sample volume limitations similar to the claims of the instant application.

The instant claims differ by reciting additional method steps and associated structure with respect to lysing the sample and reacting the analyte separated in the extraction region.

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The references of Anderson et al. and Wilding et al. both disclose that it is known in the art to include cell lysing steps and structures for preparing a liquid sample for analyte extraction and the use of reaction steps and detecting steps for analyzing the extracted analyte (nucleic acid) (See the discussions of these references previous of record).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the claims of application '443 with the additional lysing and reaction steps and components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

This is a provisional obviousness-type double patenting rejection.

13. Claims 54-56, 58-60, 62, 63, 65-68, 70, 75, 77-82, 84, 86-90, 92-97, 99, 100, 102, 104-108 and 110-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948).

Claims 1-13 of application '590 encompass a lysing method and associated structure for releasing an analyte from a liquid sample.

The above claims differ by reciting additional method steps which include analyte extraction of the lysed sample and reaction and detection of the extracted sample.

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The reference of Nelson et al. discloses a method for extracting an analyte from a liquid sample which includes an extraction region for capturing and eluting a desired analyte (See discussions of Nelson et al. above).

The references of Wilding et al. and Anderson et al. disclose that it is known in the art to provide a microchip device with cell lysing components and reaction and detection components (See the entire disclosure and discussion of these references above).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide the claims of application '590 with the additional lysing components for the known and expected result of providing a means recognized in the art to providing a nucleic acid sample while eliminating the need for sample treatment prior to introduction of the sample into the cartridge device.

With respect to the claimed reagents and reaction chambers and analysis chambers for nucleic acid, the references of Wilding et al. and Anderson et al. also discloses these features for detection of nucleic acid samples (See Figures 11A and 11B).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the system of application '590 with reagent chamber, reaction chamber, detection chambers, etc. for the known and expected result of providing a device which is capable of extracting and detecting nucleic acid samples as is suggested by the prior art references.

This is a provisional obviousness-type double patenting rejection.

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14. Claims 71, 97, 115 and 215-226 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Hansmann et al.(US 5,707,799) and Mochida (US 5,147,607).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

While the reference of Nelson et al. discloses a multitude of binding structures (See column 4, lines 24 to column 5, line 38) which can be employed in the chamber to capture a desired element of the sample liquid, the reference is silent as to the use of an array of structures extending into the chamber with an aspect ratio of at least 2:1.

The reference of Hansmann et al. discloses that it is known in the art to provide an array of pillar structures in a flow device for capturing a desired analyte in a sample fluid.

In view of this teaching, it would have been obvious to one of ordinary skill in the art based merely on the particular application in which the device of Nelson et al. is to be employed to employ an array of structures as disclosed by the reference of Hansmann et al. for the known and expected result of providing a means recognized in the art for contacting a fluid sample with a capturing surface wherein the array of pillar structures provides a large surface area for contacting.

With respect to the claimed aspect ratio, the reference of Mochida discloses an analyte capture device which includes an array of pillar structures (See Figures 19a-19c) wherein the pillars are at least twice as tall than wide.(See column 17, lines 4-13).



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In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum number, shape, size and/or dimensions of the array of pillars based on considerations such as the size of the chamber and/or the material to be captured in the chamber on the pillars while maintaining the efficiency of the separation system.

This is a provisional obviousness-type double patenting rejection.

15. Claims 72, 98 and 116 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Brunner et al.(US 5,777,141).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

The above claims differ by reciting the use of a heater in the device to improve elution efficiency.

The reference of Brunner et al. discloses that it is well known in the art to control the temperature and/or pressure within a separation column so as to control elution conditions (See column 7, line 1 to line 24).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separation chamber of the primary reference with a heater for the known and expected result of improving the separation/elution conditions within the separation chamber.

16.

This is a provisional obviousness-type double patenting rejection

17. Claims 72, 98 and 116 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/800,590 in view of Nelson et al.(5,770,029) and Wilding et al.(US 5,726,026 or 5,928,880) or Anderson et al.(US 6,168,948) and further in view of Woodward et al.(US 5,693,785) and Northrup et al.(US 5,639,423).

The combination of the claims of Application '590 with the references of Nelson et al. and either Wilding et al. or Anderson et al. has been discussed above.

The above claims differ by reciting the use of a heater in combination with the capture chamber.

The reference of Woodward et al. discloses that it is known in the art to enhance the elution of a captured analyte from a separation column using heat (See the abstract).

The reference of Northrup et al. discloses that it is known in the art to incorporate a heater device in a microchip analysis device (See column 4, lines 49-67).

In view of these teachings, it would have been obvious to provide the chamber of the modified primary reference with a heater structure for the known and expected result of

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enhancing the elution of the captured analyte from the capture zone as is recognized in the reference of Woodward et al.

This is a provisional obviousness-type double patenting rejection

*Allowable Subject Matter*

18. Claims 117-136, 227 and 228 are allowed.

19. Claims 57, 61, 73, 83, 85, 101, 103, 229 and 230 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 57, 61, 83, 101, 117-136 and 227-230, while the prior art of record discloses the use of reactions chambers which are incorporated into or coupled to the channel/chamber systems, the prior art of record fails to teach or fairly suggest 1) a reaction chamber incorporated into the channel/chamber cartridge which protrudes from the rest of the cartridge and is inserted into a thermal sleeve for heating or cooling control; 2) a reaction vessel coupled to the cartridge such that the reaction vessel can be inserted into a thermal sleeve for heating or cooling control.

With respect to claims 73, 85 and 103, while the prior art of record disclose forming a lysate in a cartridge device wherein the lysate is forced into an extraction/elution chamber, the

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prior art of record fails to teach or fairly suggest the additional step of forcing the lysate to recirculate through the capture region.

***Response to Arguments***

21. Applicant's arguments, see page 21, line 8, to page 22, line 2, filed 09 May 2003, with respect to the rejection(s) of claim(s) 54-63, 65-68, 70-75 and 77-80 under 35 USC 102 over Anderson et al. and 35 USC 103 over the combination of Nelson et al. and Wilding et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Anderson et al. in view of Nelson et al. and Wilding et al. This new rejection addresses both of applicants comments concerning the claimed filter and volume of sample relative to the lysate chamber.

22. Applicant's arguments, see page 22, lines 5-27, filed 09 May 2003, with respect to the rejection(s) of claim(s) 81-90, 92-108 and 110-116 under 35 USC 103 over the combination of the references of Anderson et al. and Nelson et al. and under 35 USC 103 over the combination of Nelson et al. and Wilding et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Anderson et al. in view of Nelson et al. and Wilding et al. This new rejection addresses both of applicants comments concerning the claimed volume of sample relative to the lysate chamber and the use of a solid phase material in a lysing chamber.

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23. Applicant's arguments, see page 23, line 6, to page 25, line 4, filed 09 May 2003, with respect to the rejection(s) of claim(s) 215-226, 229 and 230 under 35 USC 103 over the combination of Anderson et al. with Hansmann et al. and Mochida or over the combination of Nelson et al. with Wilding et al., Hansmann et al. and Mochida have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the combination of Anderson et al. in view of Nelson et al., Wilding et al., Hansmann et al. and Cantor et al.

24. With respect to the obviousness-type double patenting rejections of record, the Examiner recognizes applicants' intent to file a terminal disclaimer.

### ***Conclusion***

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The references of Swedberg et al. (US 5,571,410) and Anderson et al. (US 6,261,848) are cited as prior art references that pertain to analysis devices that include extraction chambers.

The reference of Jones (WO 95/02049) is cited as prior art that pertains to a method for capturing cells, lysing the cells and extracting and eluting the nucleic acids.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB

July 28, 2003